

**IMPROVED AUTOMATIC SURGICAL DEVICE
AND CONTROL ASSEMBLY FOR CUTTING A CORNEA**

BACKGROUND OF THE INVENTION

The present application claims priority to the following applications and/or issued patents, each of which is incorporated fully herein by reference: now pending U.S. patent application having Serial No. 09/841,165 filed April 24, 2001, which is a continuation of an earlier filed U.S. patent application, namely Serial No. 08/840,430 filed on April 29, 1997 which matured into U.S. Patent No. 6,296,649 on October 2, 2001, which itself was a continuing application based on that U.S. patent application filed on February 7, 1996 and assigned Serial No. 08/598,180 which matured into U.S. Patent No. 5,624,456 on April 29, 1997. The present application also claims priority to the following, each also incorporated fully herein by reference: a U.S. patent application filed on April 24, 1998 and assigned Serial No. 09/065,848 which matured into U.S. Patent No. 6,007,553 on December 28, 1999, which itself was a Continuation-In-Part application of an earlier filed U.S. patent application, namely, Serial No. 08/845,171 filed on April 25, 1997 which matured into U.S. Patent No. 6,051,009 on April 18, 2000. The present application further claims priority to the following, each also being incorporated fully herein by reference: a U.S. patent application filed on October 17, 2000 and assigned Serial No. 09/690,204, which is currently pending,

1 itself a continuing application of an earlier filed U.S. patent
2 application filed on November 4, 1999 and assigned Serial No.
3 09/433,478 which issued a U.S. Patent No. 6,132,446 on October
4 17, 2000; and finally, a U.S. patent application filed on
5 November 4, 1999 and assigned Serial No. 09/433,479 which is
6 currently pending.

7
8 FIELD OF THE INVENTION

9 The present invention relates to an improvement in a
10 medical apparatus used during the performance of eye surgery,
11 and more specifically, towards an automatic surgical device for
12 cutting the cornea of a patient's eye and creating a hinged flap
13 of corneal tissue. Moreover, the present invention is directed
14 towards an improved cutting blade assembly to be used in
15 conjunction with a cutting head assembly of the automatic
16 surgical device, and a control assembly for use therewith which
17 is capable of shutting off power supplied to the device when
18 problems are encountered during the surgical cutting of the
19 cornea.

20
21 DESCRIPTION OF THE RELATED ART

22 Until about twenty years ago, refractive errors of light
23 passing through the eye could only be treated with eyeglasses or
24 contact lens, both of which have well known disadvantages for
25 the user. Consequently, in the last several years, research has
26 been directed to surgical operations to change the refractive

1 condition of the eye, i.e., either to flatten or increase the
2 curvature of a patient's eye depending upon his or her
3 condition. The desired result of such surgical operations is
4 that light rays passing through the cornea will be refracted to
5 converge properly and directly onto the retina so as to allow a
6 patient to clearly see close or distant images.

7 Automated Lamellar Keratectomy (ALK) is one surgical
8 technique developed wherein the eye is first numbed by a drop of
9 anesthetic, and then a suction ring is placed on the eye to
10 carefully position the cornea (termed "centration" in the art)
11 for being cut by a very fine microsurgical instrument known as
12 a microkeratome. The microkeratome is generally a blade
13 carrying device that must be manually pushed or mechanically
14 driven in a cutting path across the suction ring simultaneous
15 with the motorized movement of the cutting element, which
16 movement is transverse to the direction of the cutting path.
17 For treating myopia pursuant to ALK procedures, the
18 microkeratome is typically used to first cut into the cornea so
19 as to raise and separate a thin layer of the anterior cornea of
20 between 100 - 200 microns in depth and about 7 millimeters in
21 diameter. Next, the microkeratome is then used to make a second
22 pass over the cornea to resect or remove a smaller part of the
23 cornea, generally about 4 to 6 millimeters in diameter, which is
24 then discarded. The anterior corneal cap which was cut away
25 with the first pass of the microkeratome is then put back into
26 its original position, without suturing, for healing to occur.

1 The desired result of this procedure is that the cornea will
2 have a new curvature because of the resected tissue, which
3 provides a new refracting surface to correct the patient's
4 original myopic condition. To correct hyperopia under ALK
5 however, the microkeratome is typically used to make a single
6 deep pass over the cornea. The cut layers are put back into
7 their original position, without any removal of any other
8 tissue. Because of the depth of the cut, the intraocular
9 pressure within the eye causes a steepening of the cornea to
10 again, provide a new refracting surface which hopefully will
11 correct the patient's original hyperopic condition.

12 Another more recent advance in surgical procedures to
13 correct refractive errors of the eye involves the introduction
14 of laser procedures. One such procedure, known as Laser
15 Intrastromal Keratomileusis, (LASIK), is currently considered
16 optimal because it allows sculpting of the cornea by a laser,
17 without damaging adjacent tissues. Moreover, with the aid of
18 computers, the laser can be programmed by a surgeon to precisely
19 control the amount of tissue removed, and significantly, to
20 permit more options for the reshaping of the cornea. Under
21 LASIK procedures, the eye is still typically positioned within
22 a suction ring and a microkeratome is typically used to cut into
23 the cornea so as to raise a thin layer of the cornea.

24 In recent years, it has been learned that regardless of
25 whether ALK or LASIK surgery is performed, the microkeratome
26 which cuts the cornea should not create a corneal cap nor

1 separate the cut corneal tissues completely from the rest of the
2 cornea. The reasons are primarily two-fold: first, the
3 possibility exists that when the corneal cap is put back in
4 place on the cornea, it will not be aligned properly with the
5 remaining corneal tissues, which has several drawbacks for the
6 patient, and second, the possibility exists that the corneal cap
7 will become lost during the surgery, and if that occurs, the
8 consequences for the patient are catastrophic. In great part to
9 overcome these problems, among others, the inventor of the
10 invention described in the present application created and
11 developed an improved surgical device for cutting the cornea
12 which automatically and reliably leaves a portion of the raised
13 and separated corneal tissues connected or "hinged" to the eye,
14 thereby forming a raised layer of corneal tissue hinged to the
15 eye, known as a corneal flap F, illustrated in Figure 1.

16 Significantly, it has been determined that the corneal flap
17 should have a depth of no less than 130 microns and no more than
18 160 microns to yield optimal results. It should be borne in
19 mind that achieving this result during surgery requires an
20 extremely precise instrument as one micron is a unit of length
21 equal to one thousandth of a millimeter. Further, it is
22 desirable, if not imperative, for the microkeratome to cut
23 across the cornea in a manner that will very finely and smoothly
24 cut the corneal tissues. In this regard, there is a need in the
25 art for improvement in that when the smoothness of a cut made to
26 the cornea by known microkeratome devices is closely examined

1 under a microscope, the cut, corneal tissue edges are seen to be
2 a bit irregular, if not slightly jagged. It would be ideal if
3 a microkeratome device were able to cut across the cornea, not
4 only so as to cut and raise the microscopically thin layer of
5 corneal tissue currently considered optimal, but to do so in a
6 manner which results in a noticeably improved cut to the cornea,
7 namely, by yielding very fine, smooth and almost undetectable
8 cut corneal tissue edges.

9 In addition, there is room for known microkeratome devices
10 to be improved with regard to the assembly required prior to
11 performing surgery on a patient's eye, as well as with regard to
12 the disassembly, sterilization and cleaning of the device, or
13 parts thereof, following surgery. Specifically, microkeratome
14 devices, and particularly, the cutting blade housed therein,
15 which penetrates into and cuts the cornea must be in a proper
16 sanitary and sterilized state until generally about the moment
17 when surgery on the eye is to begin. Known microkeratome
18 devices, however, have required that the housing for the cutting
19 blade be manipulated so as to create access to an interior
20 thereof and permit the placement of the cutting blade therein,
21 which itself must typically be handled as well, after which, the
22 housing must again be manipulated so as to close off the access
23 means, all of which has hopefully resulted in the cutting blade
24 being properly in place. This excessive manipulation required
25 of known microkeratome devices is not conducive, however, to
26 maintaining the proper sanitary and sterilized state required

1 for surgery. Moreover, in manipulating the access means of
2 certain known microkeratome devices, some surgeons have
3 unintentionally caused the cutting blade to become dislodged, or
4 worse, have even bent the cutting blade, thereby requiring the
5 assembly process to start over again. Further, the mechanisms
6 within known microkeratome devices for holding the cutting blade
7 have been designed for repeated use. This factor tends to only
8 exacerbate the problems encountered in the art in that these
9 known blade holding mechanisms should also be removed from the
10 microkeratome device following a surgery in order to be properly
11 cleaned and/or sterilized for subsequent use. The assembly and
12 disassembly of these mechanisms are not only tedious and time
13 consuming, but are fraught with the difficulties of maintaining
14 sterilization and ensuring proper re-assembly.

15 Consequently, there is a need in the art for an improved
16 microkeratome device for cutting the cornea of a patient's eye
17 which can easily receive and which facilitates the proper
18 positioning of a cutting blade therein, without excessive
19 manipulation. There is also a need for an improved cutting
20 blade assembly that facilitates easy insertion within a
21 microkeratome device, with little danger of becoming bent, while
22 simultaneously offering the user the knowledge that it is
23 securely and properly in place. Any such improved cutting blade
24 assembly should similarly be quickly and easily removed from the
25 microkeratome device, and will preferably be disposable. It
26 would be ideal if any such improved cutting blade assembly could

1 be readily packaged in containers that permit sterilization
2 prior to shipping, and which remain sterilized during shipping,
3 and further, which could be easily removed from the sterile
4 packaging for insertion into the microkeratome while maintaining
5 sterility. In this regard, any such improved cutting blade
6 assembly would ideally include an instrument which facilitates
7 the removal of the assembly from a sterile container and the
8 insertion thereof into the microkeratome, while maintaining
9 sterility.

10 Known microkeratome devices are thought to have other,
11 fairly significant deficiencies as well. For example, when a
12 surgery on a patient's eye is underway, at times the suction or
13 vacuum provided to temporarily attach the positioning ring to
14 the cornea is either broken or interrupted. Given the precision
15 cutting which is needed for such surgeries, however, it is
16 highly undesirable, for the eye to continue to be cut during
17 such situations. To date, known microkeratome devices continue
18 cutting in such situations. Thus, it would be highly beneficial
19 to provide an improved microkeratome device with a control
20 assembly that could detect problems encountered during the
21 surgical cutting of the cornea and that will shut off power
22 supplied to the device when problems are detected so as to stop
23 the cutting of the cornea by the microkeratome. Moreover, if
24 surgery on a patient's eye is proceeding well, but there is
25 sudden power loss, any such control assembly should enable the
26 microkeratome device to continue functioning during the rather

1 short duration of the operation, without interruption, both in
2 terms of continuing to ensure a power supply to the device and
3 a supply of vacuum to the positioning ring.
4

5 SUMMARY OF THE INVENTION

6 The present invention is designed to satisfy the needs
7 which remain in the art of microkeratome devices used to cut the
8 cornea of a patient's eye. In this regard, the present
9 invention is directed towards an improved microkeratome which is
10 able to cut and raise a microscopically thin layer of corneal
11 tissue in a manner that results in very fine, smooth and almost
12 undetectable cut corneal tissue edges. Along these lines, the
13 present invention is seen to include structure for retaining and
14 positioning the eye on which surgery is to be performed, a
15 cutting head assembly, including a cutting element positioned
16 therein, for cutting the cornea of the eye, and in some
17 embodiments a coupling member for detachably coupling the
18 retaining and positioning means and cutting head assembly while
19 permitting movement of the cutting head assembly relative to the
20 retaining and positioning means along a generally arcuate path.

21 In a preferred embodiment, the retaining and positioning
22 structure includes a positioning ring configured to achieve
23 temporary attachment to a portion of the eye surrounding the
24 cornea to be cut, and which exposes and presents the cornea for
25 cutting. The positioning ring may include a guide assembly
26 operably associated therewith and defining a generally arcuate

1 path. Furthermore, the cutting head assembly of the present
2 invention is structured and disposed to be cooperatively
3 associated with the positioning assembly and to be driven
4 substantially but not completely over the cornea of the eye so
5 as to cut the cornea and form the corneal flap. The cutting
6 head assembly is also, in at least one embodiment, structured
7 and disposed to be guided by the guide assembly along a
8 generally arcuate path during movement of the assembly
9 thereacross. The cutting head assembly in the illustrated
10 embodiment is seen to comprise a main housing which carries a
11 cutting element positioned therein and disposed for cutting and
12 raising the corneal flap. Moreover, in the preferred
13 embodiment, the cutting head assembly includes a flap receiving
14 gap formed within an undersurface thereof forward of the cutting
15 element for protectively receiving the corneal flap of tissue
16 formed by the forward movement of the cutting head assembly.
17 Further, the cutting head assembly may be structured and
18 disposed to be movably coupled to the positioning ring by way of
19 a coupling member which detachably couples the cutting head
20 assembly and the positioning ring and yet, permits movement of
21 the cutting head assembly relative to the positioning ring along
22 the generally arcuate path.

23 The present invention further comprises a driving assembly
24 for driving the cutting head assembly over the retaining and
25 positioning assembly, and in the preferred embodiment, may
26 include a stop assembly, which is structured and disposed to

1 limit movement of the cutting head assembly across the retaining
2 and positioning assembly. The stop assembly may be formed on
3 the cutting head assembly and may be structured and disposed to
4 engagingly abut a portion of the guide assembly so as to limit
5 further movement of the cutting head assembly at a point before
6 the cutting element has passed completely over the cornea of the
7 eye, thereby forming the corneal flap on the eye undergoing
8 surgery. In the preferred embodiment, the drive assembly is
9 operably connected to the cutting head assembly at a top surface
10 thereof and is capable of stopping and reversing the direction
11 of movement of the cutting head assembly once the stop assembly
12 has prevented movement of the cutting head assembly in a first
13 direction across the retaining and positioning assembly.

14 In addition, the present invention is directed towards an
15 improved microkeratome cutting blade assembly that permits quick
16 and easy installation and removal from the microkeratome
17 housing, without excessive manipulation, and which provides an
18 effective cut and range of movement. Preferably, the cutting
19 blade assembly of the present invention is seen to comprise an
20 improved cutting blade and blade holder. The cutting blade
21 comprises a front portion that includes a sharp, forward cutting
22 edge, a rear, trailing portion having a rear edge, and a pair of
23 side edges, at least one of which extends and tapers between the
24 front and rear trailing portions. The cutting blade, which may
25 be secured to the blade holder in any operable method, may
26 further include at least one aperture formed therein, and

1 preferably, a pair of apertures disposed in the rear, trailing
2 portion in substantially aligned relation with one another.
3 Preferably, the cutting blade is substantially flat and made of
4 stainless steel, with the front portion of the cutting blade
5 having an overall dimension which is larger than the rear
6 trailing portion. The blade holder of the improved cutting
7 blade assembly is formed so that an underside thereof is secured
8 to the cutting blade, such as at the at least one aperture on
9 the cutting blade, and so that a top side of the blade holder
10 includes structure for being operably driven by the drive
11 assembly of the microkeratome device, which may comprise a
12 recess formed within the blade holder. In the preferred
13 embodiment, the blade holder will be molded of a plastic
14 material and will be press fit during manufacture into the at
15 least one aperture on the cutting blade so as to provide an
16 integrally formed cutting blade assembly. In a most preferred
17 embodiment, the cutting blade assembly of the present invention
18 will additionally comprise a tool which facilitates the removal
19 of the cutting blade and blade holder from a sterile packing
20 container and the insertion thereof in a microkeratome device,
21 while maintaining sterility.

22 The present invention is also directed towards a control
23 assembly for a microkeratome device that is capable of detecting
24 problems encountered during the surgical cutting of the cornea
25 and either shutting off power supplied to the device, if
26 appropriate, or ensuring that power and/or a vacuum continue to

1 be supplied to the device, if appropriate.

2 The objects, features and advantages of the present
3 invention will be more readily understood upon consideration of
4 the accompanying drawings as well as the detailed description of
5 a preferred embodiment(s) for the invention, set forth below.

6
7 BRIEF DESCRIPTION OF THE DRAWINGS

8 For a fuller understanding of the nature of the present
9 invention, reference should be had to the following detailed
10 description taken in connection with the accompanying drawings
11 in which:

12 Figure 1 is schematic illustration of a cornea of an eye
13 wherein a corneal flap has been created.

14 Figure 2 is an exploded perspective view of a preferred
15 microkeratome retaining and positioning means, of a preferred
16 microkeratome cutting head assembly, as well as a preferred
17 microkeratome coupling member according to the present
18 invention.

19 Figure 3 is a cross sectional view of the retaining and
20 positioning means shown in Figure 2.

21 Figure 4 is a partial side view of the preferred
22 microkeratome illustrated in Figure 2 in assembled form and in
23 position on a patient's cornea.

24 Figure 5 is a partial cross sectional view of the preferred
25 microkeratome illustrated in Figure 4.

26 Figure 5-A is a partial cross sectional view of the

1 preferred microkeratome in a partially disassembled state so as
2 to illustrate the improved access means, without a cutting blade
3 assembly inserted therein.

4 Figure 6-A is a side view of the cutting blade assembly
5 according to the present invention in a preferred embodiment.

6 Figure 6-B is a top plan view of the cutting blade assembly
7 illustrated in Figure 6-A.

8 Figure 6-C is a bottom view of the cutting blade assembly
9 illustrated in Figure 6-A.

10 Figure 7 is a top plan view of the cutting blade assembly
11 of the present invention in an alternative embodiment.

12 Figure 8 is a side view of a tool which facilitates the
13 removal of the cutting blade assembly shown in Figures 6 and 7
14 from a sterile packing container and the insertion thereof in a
15 microkeratome device, while maintaining sterility.

16 Figure 9 is an isolated perspective view of the drive means
17 for the preferred microkeratome device and illustrating the
18 operation and interconnection of the worm, worm gear, and
19 oscillating shaft with the means of the blade holder, in the
20 form of a recess, for being operably driven by the drive means
21 of the microkeratome device.

22 Figure 10-A is a front schematic illustration of the
23 preferred microkeratome in use on both a patient's left and
24 right eyes and illustrating the cutting head assembly in the
25 initial position.

26 Figure 10-B is a front schematic illustration of the

1 preferred microkeratome illustrated in Figure 10-A but depicting
2 the cutting head assembly in the movement stopped position
3 wherein a corneal flap has been formed with the resulting hinged
4 portion being oriented so as to cooperate with the blinking of
5 the eye following surgery.

6 Figure 11 is a perspective, partial cut away view of a
7 preferred control assembly configuration according to the
8 present invention which is to be used with a microkeratome
9 device such as illustrated in Figure 2.

10 Figure 12 is an isolated diagram of the configuration of a
11 preferred optic coupler for the control assembly according to
12 the present invention.

13 Like reference numerals refer to like parts throughout the
14 several views of the drawings.

15
16 DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

17 As illustrated throughout the Figures, the present
18 invention is directed towards an improved automatic
19 microkeratome device for smoothly cutting the cornea of an eye,
20 generally indicated by reference numeral 10, and towards a
21 cutting blade assembly therefor, generally indicated by
22 reference numeral 105, and towards a control assembly therefor,
23 generally indicated by reference numeral 200.

24 The preferred and improved automatic microkeratome device
25 of the present invention, which is structured to cut
26 substantially but not completely across the cornea of a

1 patient's eye so as to raise a thin layer thereof and create a
2 hinged flap of corneal tissue, will be discussed first. As
3 illustrated in Figures 2 and 3, the preferred microkeratome
4 device 10 includes means 30 for retaining and positioning the
5 eye on which surgery is to be performed. The retaining and
6 positioning means 30, which may be made of high grade stainless
7 steel, preferably comprise a positioning ring 32 having an
8 aperture 33 formed therein. The aperture 33 is sized to permit
9 the cornea C, of the eye to pass therethrough and be exposed, as
10 depicted in Figure 3. As illustrated, the positioning ring 32
11 is preferably defined by a generally tear-drop shape.

12 Positioning ring 32 further includes means for being
13 temporarily attached to a portion of the eye surrounding the
14 cornea on which surgery is to be performed. Ideally, the
15 temporary attachment means include suctioning assembly. For
16 example, positioning ring 32 preferably includes a connection
17 member 37, which as illustrated in Figure 2 and 3, is in fluid
18 communication with an undersurface of positioning ring 32.
19 Connection member 37 is adapted to be interconnected with a
20 vacuum hose 202, which as shown in Figure 11, may be connected
21 to a vacuum pump 210, such that when suction occurs, the
22 undersurface of positioning ring 32 forms a seal about and is
23 retained about the corneal portion of the eye which is about to
24 undergo surgery. Further, the structure of positioning ring 32,
25 accompanied by the suctioning, acts to properly position the
26 cornea C, for surgery and to maintain the position during

1 surgery as well. Typically, a vacuum of about 25 inches of Hg
2 at sea level will be used.

3 The retaining and positioning means 30 further include a
4 guide means or guide assembly 40 formed thereon, best
5 illustrated in Figure 3. Guide means 40 may be formed directly
6 on the positioning ring 32, so as to be integral therewith, or
7 may be operably connected thereto as a separate element. In any
8 event however, the guide means 40 will be disposed on
9 positioning ring 32 so as to guide and facilitate movement of
10 the cutting head assembly 50, discussed below, during the
11 surgical cutting of the cornea. Referring to Figure 3, in the
12 preferred embodiment, the guide assembly 40 are seen to comprise
13 a channel member 42, which extends along a length of at least
14 one side of positioning ring 32 and preferably, on an upper
15 surface of positioning ring 32. It will also be appreciated
16 from the drawings that channel member 42 extends across ring 32
17 in an arcuate or semi-circular path. In the most preferred
18 embodiment channel member 42 is formed by the interconnection of
19 two separate elements, namely, an upwardly and arcuately
20 extending sidewall 36 formed on positioning ring 32, and a
21 toothed track 43 which is interconnected with sidewall 36.
22 Still referring to Figure 3, in the most preferred embodiment,
23 positioning ring 32 is seen to include the upwardly and
24 arcuately extending sidewall 36 having a ridge 38 formed on an
25 upper surface thereof, and extending partially if not completely
26 along, at least one side of positioning ring 32. Further, in

1 this preferred embodiment, the toothed track 43 is structured to
2 be operably connected to ridge 38 by way of mating structure.
3 For example, the mating structure can be in the form of a
4 receiving groove disposed on the undersurface of toothed track
5 43, and/or by way of conventionally known fasteners 39' such as
6 screws, rivets, etc. which may pass through positioning ring 32
7 at apertures 39 and extend into toothed track 43. As further
8 illustrated in Figure 3, toothed track 43 is seen to include a
9 lip 43' which is sized and dimensioned to protrude beyond the
10 vertical plane formed by sidewall 36. Thus, the guide assembly
11 40 in the form of a generally "C" shaped channel member 42 is
12 comprised by the combined structure of sidewall 36 and toothed
13 track 43, having lip 43'. It will be appreciated that toothed
14 track 43 also cooperates with the drive assembly 80 (see Figures
15 4 and 9) so as to drive the cutting head assembly 50 across
16 positioning ring 32, as more fully discussed below, and may be
17 on an interior or the preferred exterior of the drive assembly
18 80.

19 The guide assembly 40 may further or alternately comprise
20 a rigid upstanding member 44 disposed on the retaining and
21 positioning means 30, and generally opposite the toothed track
22 43. As will again be appreciated from the drawings, in the
23 preferred embodiment, wherein positioning ring 32 is of a tear-
24 drop shape, rigid upstanding member 44 comprises a post member
25 45 securely connected to positioning ring 32 on an upper surface
26 thereof at or near a tip 35 thereof. From the explanation which

1 follows, it will become clear that in the preferred, illustrated
2 embodiment, channel member 42 and rigid upstanding member 44
3 permit the cutting head assembly 50 of this invention to become
4 effectively guided and securely received on the positioning ring
5 32 in two places while still permitting the cutting head
6 assembly 50 to be smoothly and slidably moved over positioning
7 ring 32 along a generally arcuate path, by way of a pivoting
8 motion about rigid upstanding member 44.

9 Referring now to Figure 2, the preferred microkeratome
10 device is seen to include a cutting head assembly 50. A primary
11 purpose of the cutting head assembly 50 is to house a cutting
12 element 70 such as a cutting blade, see Figure 5, with a cutting
13 surface operatively exposed therefrom. As such, upon the
14 cutting head assembly 50, with the cutting element 70
15 operatively disposed therein, being moved across the cornea
16 retained within positioning ring 32, the cornea may be precisely
17 cut by cutting element 70. To accomplish this, cutting head
18 assembly 50 includes a main housing 51 containing the cutting
19 element 70. Additionally, included in the main housing 51 is an
20 aperture 58 structured and disposed to permit the drive assembly
21 80 to be operably connected thereto, such as from the preferred
22 vertical orientation, (see Figures 4 and 9) and in the
23 illustrated embodiment, to thereby drive the cutting head
24 assembly 50 across positioning ring 32 in order to effectively
25 cut the cornea. Further, as the cutting head assembly 50 must
26 be driven in a smooth and controlled manner across the cornea,

1 housing 51 includes a track assembly 60 which is structured and
2 disposed for mating communication with and tracking within
3 channel member 42, of positioning ring 32, in order to help
4 precisely guide the cutting head assembly 50, and therefore the
5 cutting element 70, along the defined arcuate path. Finally, as
6 a feature of the preferred microkeratome device is to cut a
7 portion of the cornea without completely severing it, abutting
8 or stop means 65 are provided, which serve the purpose of
9 limiting and preferably, completely stopping the movement of the
10 cutting head assembly 50 from cutting completely across the
11 cornea, that is, before the assembly has passed completely over
12 the cornea. The abutting means or stop assembly are preferably
13 disposed on the main housing 51. These features will be
14 discussed in more detail below.

15 Still referring to Figure 2, the preferred microkeratome
16 device is also seen to include a coupling member 90. Coupling
17 member 90 is structured and disposed to movably couple the
18 cutting head assembly 50 to the positioning ring 32 while
19 simultaneously permitting movement of the cutting head assembly
20 50 relative to positioning ring 32. As illustrated in Figure 2,
21 coupling member 90 comprises two segments: a) a retaining
22 segment 92 and b) a pivot segment 95. The retaining segment 92
23 is structured and disposed to be fitted onto a top wall surface
24 56' of main housing 51 and may include downwardly depending
25 flanges 91, 93 to snugly receive and grip a portion of housing
26 51 therebetween. The retaining segment 92 also includes an

1 aperture 94 formed therein to correspond to aperture 58 of
2 housing 51. As such, aperture 94 is sized and configured to
3 allow passage of the driving shaft of the driving means 80
4 (shown in Figures 4 and 9) therethrough and into aperture 58 of
5 the housing 51. Thus, in assembled form, coupling member 90 is
6 securely yet removably coupled to head assembly 50 as a result
7 of the engagement of the driving assembly 80 with the housing 51
8 through retaining segment 92. Turning to the pivot segment 95
9 of coupling member 90, it is structured and disposed to be
10 coupled to rigid upstanding member 44 of positioning ring 32 and
11 to permit coupling member 90, and accordingly, the cutting head
12 assembly 50 connected thereto, to pivotally move about post
13 member 45. Preferably, pivot segment 95 includes a bushing 97
14 having a bore 96 formed therein, which is sized to receive a
15 substantial height of post member 45, thereby captivating it
16 therein. Further, the pivot segment 95 preferably includes
17 maintaining means 46, see Figure 3, for maintaining rigid
18 upstanding member 44 within bushing 97 and engagement means 98
19 for maintaining bushing 97 over rigid upstanding member 44. As
20 illustrated in Figures 2 and 3, the maintaining means 46
21 preferably include an enlarged head 47 on rigid upstanding
22 member 44, and an annular recess 48 or taper about the neck
23 section of upstanding member 44. As illustrated, the engagement
24 means 98 preferably comprise a threaded shaft which passes
25 through a sidewall of bushing 97 and can be selectively moved
26 into engagement with upstanding member 44 by rotating handle 99

1 and causing a tip thereof to extend into the annular recess 48,
2 thereby preventing removal of the pivot segment 95 from the
3 upstanding member 44, when surgery is to take place. It will be
4 therefore be appreciated that in assembled form, the engagement
5 means 98 and maintaining means 46 cooperate to permit coupling
6 member 90 and cutting head assembly 50 to rotate about
7 upstanding member 44 while preventing bushing 97 from sliding up
8 and off of upstanding member 44. It will also be appreciated
9 that in assembled form, upstanding member 44 acts as guide
10 assembly for enabling the cutting head assembly 50 to be driven
11 along an arcuate path in a smooth and controlled manner across
12 positioning ring 32 and thus, the cornea C.

13 With reference to Figure 2, the cutting head assembly 50 of
14 the preferred microkeratome device as well as its operation will
15 now be described in more detail. As previously recited, the
16 cutting head assembly 50 comprises the main housing 51 which
17 includes a top surface 56', a bottom wall, and a surrounding
18 sidewall structure 53 defining a front end face 52, and an
19 oppositely disposed rear end face 54. Because during surgery,
20 the cutting head assembly 50 is driven across positioning ring
21 32 along an arcuate path, front end face 52 preferably defines
22 a tapered nose to cooperate with the arcuate path of channel
23 member 42. Also as previously recited, the main housing is
24 structured to contain the cutting element 70, such as a cutting
25 blade, and to operatively expose a cutting surface thereof. In
26 order to accomplish this, the main housing 51 is preferably

1 structured to define an interior chamber 88, therein, see Figure
2 5, which is structured to receive in a cutting position and to
3 accommodate the operation of the cutting element 70 during
4 surgery, and preferably, of a blade cutting assembly 300,
5 described more fully below. A cutting opening 56 is formed at
6 a bottom of housing 51 so as to expose a cutting surface of
7 cutting element 70, as is best illustrated in Figure 5.

8 Additionally, in order to permit a used cutting element 70
9 to be removed and replaced, housing 51 includes access means 55.
10 In one embodiment, and as seen in Figure 5, access means 55 at
11 least partially form bottom wall of housing 51 near rear end
12 face 54, and ideally, comprise a door member 57 which is
13 hingedly connected to the surrounding sidewall structure 53 at
14 rear end face 54. Door member 57 is movable between a closed
15 operative position for surgery and an open position for
16 permitting a used or contaminated cutting element 70 to be
17 removed from the housing 51 and replaced with a new or sterile
18 cutting element. Door member 57 may be selectively maintained
19 in the closed position by conventionally known fasteners as
20 depicted in Figure 5. It should be noted that the door member
21 57 does not completely bridge the cutting element 70, which is
22 thought to offer a sturdier and less fragile structure so as to
23 avoid bending the cutting element when it is inserted and closed
24 into position for use within the microkeratome.

25 A unique feature of the present invention, however, is to
26 provide the cutting head assembly 50 of the microkeratome device

1 with improved access means, see Figure 5-A, indicated generally
2 by reference numeral 155, such that in preparation for surgery,
3 a fresh and sterilized cutting element can be easily and quickly
4 inserted within the cutting head assembly 50, with minimal
5 handling so as to maintain it in a sanitary condition.
6 Preferably, the improved access means 155 permit a fresh cutting
7 element 70, and ideally, a cutting blade assembly 300 which
8 includes both a cutting blade and a blade holder, described
9 below, to be slidably inserted into the cutting head assembly,
10 50 and to be easily and yet properly secured in place therein in
11 order for surgery to take place. To accomplish this, the
12 improved access means 155 preferably comprise a side entry,
13 access opening formed in the cutting head assembly 50. As
14 illustrated in Figure 5-A, more preferably, the surrounding
15 sidewall structure 53 of the cutting head assembly 50 is
16 structured to include an access opening 156 formed therein which
17 further, is disposed to generally correspond and align with the
18 location of interior chamber 88 of the cutting head assembly 50,
19 so that the cutting element 70 may be received in a proper
20 cutting position within the cutting head assembly 50 for surgery
21 to take place. Ideally, the access opening 156 is structured
22 and disposed to extend completely through the cutting head
23 assembly 50 from one side of the surrounding sidewall structure
24 53 to the other, so that the cutting element 70 can be easily
25 inserted from either side of the cutting head assembly 50. It
26 should be appreciated from the foregoing that the improved

1 access means 155 are additionally structured and disposed to
2 permit easy and quick removal of a used and contaminated cutting
3 element 70 from the cutting head assembly. It should further
4 be appreciated that while the door member 57 of the cutting head
5 assembly 50 can also be moved to an open position so as to
6 permit insertion of a cutting element 70 within the cutting head
7 assembly 50, the door member is preferably only moved to the
8 open position to permit cleaning of other internal mechanisms
9 disposed within the cutting head, whenever needed.

10 With reference to Figure 5, the cutting element 70 will now
11 be discussed. First, in the preferred embodiment, the cutting
12 element 70 is disposed within the main housing 51 at about 20 to
13 30 degrees from the horizontal plane. Further, the cutting
14 element 70 preferably includes a blade having a sharpened
15 cutting edge 71, the cutting tip of which is preferably formed
16 to have an angle of approximately and generally between 5 to 10
17 degrees from the horizontal axis of the blade. To accomplish
18 these preferred goals, in a preferred embodiment, the cutting
19 element 70 comprises a cutting blade operably connected to a
20 blade holder 72. The blade holder is in turn, operably
21 connected and disposed within the interior chamber 88 of the
22 cutting head assembly 50 in communication with the drive
23 assembly 80, see Figure 9, which are in turn operably coupled to
24 the housing 51 of the cutting head assembly 50, and
25 microkeratome generally. As has been described, the drive
26 assembly 80 imparts an oscillating movement to the blade holder

1 72, thereby causing the blade holder 72 and blade 71 connected
2 thereto, to move back and forth within the interior chamber 88
3 of the cutting head assembly 50 and generally between opposite
4 walls of the surrounding sidewall structure 53 thereof.
5 Accordingly, the interior chamber 88 within housing 51 will be
6 sized to receive both the cutting element, such as a cutting
7 blade 70 and blade holder 72, and to permit the oscillating
8 cutting movement of same within housing 51. So as to offer an
9 improved microkeratome and cutting blade assembly that is able
10 to cut and raise a microscopically thin layer of corneal tissue
11 in a manner that results in very fine, smooth and almost
12 undetectable cut corneal tissue edges, in a preferred
13 embodiment, the drive assembly 80 will at least cause the blade
14 holder 72 and blade 71 to oscillate at a very rapid rate, higher
15 than that accomplished by other devices, such as generally about
16 5,000 to 10,000 times per minute, and ideally about 8,500 times
17 per minute so as to offer an optimal corneal cut. Further in
18 this regard, and as explained further below, the drive assembly
19 may also preferably drive the cutting head assembly 50 across
20 the positioning ring 30 and eye held therein, at a speed which
21 takes the cutting head assembly 50 generally between 3 to 6
22 seconds, and ideally about 4 or 5 seconds. These preferred
23 ranges for the cutting speeds of the microkeratome are thought
24 to offer optimal and markedly improved cutting of the corneal
25 tissues.

26 In addition, in order to accomplish the desirable goal of

1 easily and quickly installing the cutting element 70 within the
2 cutting head assembly 50, without excessive handling so as to
3 maintain sterilization, the present invention comprises a
4 cutting blade assembly, illustrated in Figures 6 - 8 and
5 generally indicated by reference numeral 300. The cutting blade
6 assembly 300 of the present invention is seen to comprise an
7 improved cutting blade 310 and blade holder 320. The cutting
8 blade 310 comprises a front portion 312 that includes a sharp,
9 forward cutting edge 313, a rear, trailing portion 314 having a
10 rear edge, 315, and a pair of side edges, 316, 317 that extend
11 and taper between the front and rear trailing portions. In a
12 preferred embodiment, the rear edge 315 is generally parallel to
13 the forward cutting edge 313 of front portion 312. Also, the
14 cutting blade 310 further includes at least one aperture, 318
15 formed therein, and preferably, a pair of apertures, 318 and 319
16 which are ideally circular in shape and disposed in the rear,
17 trailing portion 314 in general alignment with one another.
18 Preferably, the cutting blade 310 is substantially flat and made
19 of stainless steel, with the front portion 312 of the cutting
20 blade having an overall dimension which is larger than the rear
21 trailing portion 314. In one embodiment, shown in Figure 7, the
22 side edges 316, 317 of the improved cutting blade 310' which
23 extend between the front portion 312 and rear trailing portion
24 314, are rounded. This feature readily permits the operation of
25 the cutting assembly 300 within the preferred microkeratome
26 device that moves along an arcuate path over the position ring

1 32. More specifically, the cutting blade 310' shown in Figure
2 7 is structured so that when it is oscillating during a surgery,
3 wherein all or part of the blades' side edges might momentarily
4 extend beyond the surrounding sidewall structure 53 of the
5 cutting head assembly 50, it will not contact the positioning
6 ring 32 nor otherwise interfere with the movement of the cutting
7 head assembly 50 thereacross, along an arcuate path. The
8 cutting blade 310, 310' can be formed to have other shapes to
9 accomplish this same goal. For example, and as illustrated in
10 Figures 6-A to 6-C, in a more preferred embodiment, the front
11 portion 312 of the cutting blade 310 has a generally rectangular
12 shape and the rear trailing portion 314 has a generally
13 trapezoidal shape, such that the side edges 316, 317 thereof
14 taper from a wider dimension of the front portion 312 to a
15 smaller dimension in the rear trailing portion 314.

16 The cutting blade assembly 300 further comprises an
17 improved blade holder 320. Blade holder 320 is formed so that
18 an underside 321 thereof is secured to the cutting blade 310 at
19 the at least one aperture 318 on the cutting blade, and so that
20 a top side, 322, of the blade holder 320 includes means 325 for
21 being operably driven by the drive assembly 80 of the
22 microkeratome device. In the preferred embodiment, means 325
23 comprise a recess 326 formed within the blade holder, ideally
24 having an oval shape, although the blade holder 320 could be
25 formed to include a slot, groove or other shaped recess without
26 departing from the scope of the present invention. Also in the

1 preferred embodiment, the blade holder 320 will be molded of a
2 plastic material and will be press fit during manufacture into
3 the at least one aperture 118 on the cutting blade 310 so as to
4 provide an integrally formed cutting blade assembly. It should
5 be pointed out that by integrally forming the cutting blade 310
6 and blade holder 320, both parts which are contaminated during
7 surgery, the cutting blade assembly 300 can be more readily
8 removed from the cutting head 50 of the microkeratome, and
9 further, if the blade holder 320 is formed of plastic, the
10 cutting blade assembly 305 can be readily disposed of.
11 Preferably, the blade holder 320 includes at least one lock
12 segment 328 on its undersurface 321, which is structured and
13 disposed to extend through the aperture 318 formed in the
14 cutting blade 310 so as to become secured thereto. Most
15 preferably, the blade holder includes a pair of lock segments
16 formed to be circular in shape and which are structured to be
17 snugly received within the preferred pair of apertures 318, 319
18 formed on the blade 310. Also in the preferred embodiment, the
19 lock segment 328 includes a flanged portion 329 which is
20 structured to engage at least partially about an edge of the
21 aperture formed within the blade 310.

22 Referring now to Figure 8, in a most preferred embodiment,
23 the cutting blade assembly 300 of the present invention is seen
24 to additionally comprise a tool 330 which facilitates the
25 removal of the cutting blade 310 and blade holder 320 from a
26 sterile packing container and the insertion thereof in a

1 microkeratome device, while maintaining sterility. Preferably
2 this tool is in the form of a handle assembly 360 connected to
3 the blade holder 320 and structured to facilitate the
4 introduction of the cutting blade assembly 300 into the access
5 opening 156 of the cutting head assembly 50. In the preferred
6 embodiment, the handle assembly 360 includes an elongate stem
7 362 structured to be threadingly coupled to the blade holder,
8 ideally along a side wall thereof, so as to facilitate the
9 introduction and installation of the cutting blade assembly 300
10 to and within the cutting head assembly 50. If desired, in this
11 embodiment or in other embodiments, the handle assembly can be
12 structured to permit the elongate stem 362 to be reconnected
13 with the blade holder so as to remove a contaminated cutting
14 blade assembly from the cutting head assembly 50, following a
15 surgery. In an alternative preferred embodiment, the handle
16 assembly 360 may include an elongate stem integrally formed with
17 the blade holder and structured to be separated therefrom upon
18 introduction and installation of the cutting blade assembly
19 within the cutting head assembly 50. It should be appreciated
20 that in this alternative preferred embodiment, the handle
21 assembly may be comprised of a suitable plastic material so that
22 it can be integrally formed with the preferred blade holder 320,
23 and the entire cutting blade assembly can then be readily
24 packaged in containers that permit sterilization prior to
25 shipping, and which remain sterilized during shipping. In this
26 way, the handle assembly 360 with the cutting blade assembly 300

1 connected thereto, can be easily removed from the sterile
2 packaging and the handle assembly 360 used to quickly and easily
3 insert the cutting blade assembly 300, while maintaining it in
4 a sanitary condition, into the microkeratome's cutting head
5 assembly, 50. Thereupon, the handle assembly 360 can be broken
6 off from the cutting blade assembly 300 and discarded or
7 otherwise disposed of.

8 Referring back now to Figure 5, other features of the
9 preferred microkeratome device will be described. In the
10 preferred embodiment, the housing 51 of cutting head assembly 50
11 will include depth adjusting means 75 for adjusting the depth at
12 which cutting element 70 cuts into the cornea. As illustrated
13 in Figure 5, the depth adjusting means 75 are preferably
14 disposed at the front end face 52 of main housing 51 and form at
15 least a portion of the bottom wall of housing 51 near front end
16 face 52. Preferably, the depth adjusting means 75 comprise a
17 separate nose segment 76, which is structured to be securely,
18 yet removably interconnected with housing 51 by way of a
19 conventionally known fasteners 74 such as a screw, a bolt, etc.
20 Preferably, the nose segment 76 comprises an engagement segment
21 77 and a variable depth plate member 78. Engagement segment 77
22 preferably includes a terminal end 79 which is formed to define
23 an inverted "V" shape, and preferably extends across the width
24 of the nose segment 76. This structure is sized and configured
25 to be received and to nest within a corresponding void, also
26 shaped like an inverted "V", formed within housing 51 on and

1 between oppositely disposed sidewall structures 53, adjacent
2 front end face 52. It will be appreciated that this structure
3 permits a highly stable nesting or dwelling of terminal end 79
4 within housing 51 even as the cutting head assembly 50 is moved
5 along an arcuate path over positioning ring 32. Further, as
6 illustrated, variable depth plate member 78 is preferably
7 integral with engagement segment 77 and is disposed
8 substantially in the horizontal plane. Variable depth plate
9 member 78, has a depth depicted as "H" in Figure 5, which is a
10 dimension pre-selected by the surgeon to correspond the desired
11 depth of the cut to be made into the cornea. Another feature of
12 the present invention is to provide a plurality of nose segments
13 76, each including a plate member 78 having a differently
14 dimensioned depth "H". It will be appreciated from Figure 5
15 that there is an inverse relationship between the depth of plate
16 member 78 and the depth of the cut to the cornea as the cutting
17 head assembly 50 proceeds forward during surgery in the
18 direction of the arrow "A" and pushes down on the cornea. For
19 example, a plate member 78 having a larger depth "H" will shield
20 more of the blade's cutting edge 71 whereas a plate member 78
21 having a smaller depth "H" will expose more of area above the
22 blade's cutting edge. It will thus be recognized that the
23 cutting head assembly 50 is designed to be interchangeable with
24 differently sized depth adjusting means 75 so as to precisely
25 meet the needs of the patient undergoing surgery. Ideally, the
26 present invention will offer two differently sized nose segments

1 76, namely one sized for 130 microns and another for 160 microns
2 which are currently the most desirable depths for cutting into
3 the cornea and exposing same for reshaping.

4 As has been described, housing 51 of cutting head assembly
5 50 also includes tracking means 60. Referring to Figure 2,
6 tracking means 60, which in the preferred embodiment are
7 disposed on a lower peripheral zone of housing 51, are
8 structured for mating communication with and tracking within
9 channel member 42, see Figure 3, of positioning ring 32. For
10 example, in the preferred embodiment the tracking means 60 are
11 disposed on the depth adjusting means 75 and are integral with
12 and planar to the variable depth plate member 78 in the form of
13 a flange 62, see Figure 2. Preferably, flange 62 extends out
14 beyond the periphery defined by surrounding sidewall 53 of
15 housing 51 in generally perpendicular relation thereto.
16 Further, although the cutting head assembly 50 is designed to
17 receive nose segments 76 having variable depth plate members 78,
18 flange 62 which extends therefrom is of a uniform height so as
19 to correspond and effect mating communication with and tracking
20 within channel member 42, of positioning ring 32. Although
21 flange 62 could extend only from one side of the housing 51, in
22 the preferred embodiment, flange 62 is disposed on each side of
23 variable depth plate member 78, thereby facilitating use of the
24 present invention on either a patient's left or right eye.

25 Also as previously recited, the main housing 51 includes
26 abutting or stop means 65 which serve the purpose of limiting

1 and preferably stopping, the forward movement of cutting head
2 assembly 50 across positioning ring 32. In the preferred
3 embodiment, stop means 65 are formed generally at rear end face
4 54 on surrounding sidewall structure 53 and are seen to comprise
5 a shoulder 66 formed at the juncture between sidewall structure
6 53 and rear end face 54 of the housing 51, which shoulder is
7 sized to be too large to pass within the channel member 42 of
8 the guide means 40, thereby preventing any further forward
9 motion of the head assembly 50 across positioning ring 32. When
10 abutting engagement occurs between shoulder 66 and channel
11 member 42, by way of lip 43', the driving means 80 can be
12 stopped and then reversed to permit movement of the cutting head
13 assembly 50 in the opposite direction. As has been described,
14 it has been determined in recent years that in performing
15 surgery on the cornea, the layers of the cornea which are cut
16 should not be completely severed. A unique feature of the
17 cutting head assembly 50 and of this invention 10 is that the
18 cutting of the cornea, C, results in the formation of a corneal
19 flap F, as illustrated in Figure 1, which is also safely
20 preserved by the assembly 50. To preserve the corneal flap F,
21 housing 51 includes a flap receiving gap 59 formed within
22 housing 51. As illustrated in Figure 2 and more clearly in
23 Figure 5, flap receiving gap 59 is disposed generally near the
24 front end face 52 of housing 51 and more particularly, is
25 defined by a gap formed just forward of the blade's cutting edge
26 71 and just rearward of variable depth plate member 78. Thus,

1 flap receiving gap 59 is disposed on an undersurface of housing
2 51 and extends upwardly and into housing 51. Ideally, flap
3 receiving gap 59 extends through the opposite sidewall structure
4 53 of housing 51.

5 In preparation for cutting the cornea with the preferred
6 microkeratome device: a) a sterilized improved cutting blade
7 assembly 300 is slidably moved into position within the cutting
8 head assembly 50, and b) the coupling member 90 is mounted on
9 the cutting head assembly 50 and the drive means 80 connected to
10 and engaged therewith. Referring to Figure 2, as an additional
11 feature, the cutting head assembly 50 may include indicia 67 for
12 indicating to a surgeon which eye the device is in position to
13 cut. For example, it is preferred that indicia such as the
14 letter "L" as an abbreviation for "Left" or "left eye" and the
15 letter "R" as an abbreviation for "Right" or "right eye" be
16 utilized, or their equivalents in words or abbreviations in a
17 foreign language or symbols. This indicia will preferably
18 appear on opposite sides of the surrounding side wall structure
19 53 of the main housing 51 of the cutting head assembly 50, in a
20 location which will be selectively concealed by the coupling
21 member 90. In particular, when operably coupled with the
22 cutting head assembly 50 and disposed over so as to cut the
23 right eye, the coupling member 90 extends down the left side of
24 the main housing 51 of the cutting head assembly 50, leaving
25 only the right side, and preferred "R" indicia positioned
26 thereon, visible. Conversely, when assembled to cut the left

1 eye, the coupling member 90 extends down the right side of the
2 housing 51, leaving only the left side and the indicia
3 positioned thereon readily visible. As such, it is seen that a
4 further safety feature directed towards ensuring proper
5 alignment of the device on a patient's eye is achieved.

6 To continue, once the positioning ring 32 has been
7 centrated on the eye with a proper vacuum applied to temporarily
8 attach it thereto, c) the tracking means 60 of the head assembly
9 50 can be matingly connected to the guide means 40 of
10 positioning ring 32 in an initial or start position. Once power
11 is supplied to the microkeratome device, the cutting head
12 assembly 50 may move across the positioning ring 32 with cutting
13 of the cornea C, taking place until the stop means 65 contact
14 channel member 42 of the positioning ring 32, to limit and
15 preferably, prevent any further forward motion of the assembly.
16 It should also be clear that in this stopped position, the
17 cutting element 70 has not moved completely across the cornea C,
18 but rather has cut a portion of the cornea up until this point,
19 creating a corneal flap which is left attached to the cornea as
20 designated by the area marked "F" which is shown in the Figures
21 10-A and 10-B. Moreover, as illustrated in Figure 5, the
22 corneal flap created has been directed by the forward movement
23 of the assembly, upwardly and into flap receiving gap 59 of
24 housing 51 to be preserved and kept clear of cutting element 70.
25 Once the assembly has been stopped as in Figure 10-B, the drive
26 means 80 can be reversed to permit movement of the cutting head

1 assembly 50 in the opposite direction, which does not result in
2 any further cutting of the cornea, but rather, in the safe
3 removal of the corneal flap F out of flap receiving gap 59 of
4 housing 51. Thus, when the cutting head assembly 50 returns
5 through to a position analogous to that shown in Figure 10-A, it
6 can be disengaged from the retaining means 30. The corneal flap
7 F can then be maneuvered so as to permit the cornea to be
8 reshaped, preferably by way of a laser surgical procedure. Once
9 the surgery has been completed, the corneal flap is returned to
10 a covering relation over cornea.

11 Another unique feature of the present invention is not only
12 that a corneal flap can be created, but significantly, that the
13 corneal flap is positioned in such a way that the blinking of
14 the eye will not improperly position the corneal flap on the
15 cornea following surgery. Referring again to Figures 10-A and
16 10-B, the preferred microkeratome device is schematically
17 illustrated on both a patient's left and right eyes. As
18 depicted in Figure 10-A, reference points of the work
19 environment can be equated with the position of some numerals on
20 the face of a clock. Thus, in Figure 10-A, it will be noted
21 that with respect to the patient's left eye, the cutting head
22 assembly 50 in the initial position is preferably disposed at a
23 generally five o'clock position. With respect to the patient's
24 right eye, the cutting head assembly 50 in the initial position
25 is preferably disposed at a generally seven o'clock position.
26 Turning now to Figure 10-B, the cutting head assembly 50 is

1 shown to have moved towards a position generally aligned with
2 the twelve o'clock position, wherein the stop means 65 are in
3 abutting engagement with channel member 42 of the positioning
4 ring 32, such that any further forward motion of the assembly is
5 prevented. It will thus be appreciated that regardless of
6 whether the surgical procedure is being performed on a patient's
7 left or right eye, the cutting head assembly 50 is preferably
8 aligned generally with a twelve o'clock position. It will also
9 be appreciated from Figure 10-B that the resulting corneal flap
10 F, remains attached to the cornea at an upper region thereof.
11 As a result, following the surgical procedure to reshape the
12 cornea, the orientation of the corneal flap will be in generally
13 the same direction as the natural blinking action. That is, it
14 is believed that the downward blinking motion of the patient
15 will tend to stroke the corneal flap down and thereby assist
16 with maintaining the corneal flap in proper re-position on the
17 cornea so as to avoid the development of astigmatism.

18 Referring now to Figure 9, the present invention includes
19 a drive assembly 80 both: a) for driving the cutting head
20 assembly 50 across the previously described eyeball retaining
21 and positioning means 30; and/or b) for causing the cutting
22 element 70 to oscillate back and forth within housing 51. The
23 drive assembly 80 in a most preferred embodiment will drive the
24 cutting head assembly 50 across the eyeball retaining and
25 positioning means 30 and eye held therein, at a speed which
26 takes the cutting head assembly generally between 3 to 6 seconds

1 in the first direction, and similarly in the opposite direction.
2 Also, in a preferred embodiment, the drive assembly 80 include
3 among other items, discussed below, a motor 100, which is
4 electrically operated and more preferably, a micromotor capable
5 of operating at a constant and uniform speed, regardless of the
6 load. Specifically, under normal circumstances the natural
7 resistance encountered by the cutting head assembly 50, as it is
8 driven over the cornea, would result in an increased torque load
9 upon the micromotor, which would tend to cause a voltage drop in
10 the internal resistance of the motor 100 and therefore a drop in
11 speed. While some known systems for microkeratome devices
12 attempt to avoid excessive drops in speed by incorporating an
13 overpowered motor to keep losses below a 10% slow down, the
14 motor 100 of the present invention is preferably equipped to
15 monitor current flowing therethrough, such as by using an op
16 amp, and to utilize that information to control the applied
17 voltage and maintain a generally constant speed. This
18 monitoring and compensation, sometimes referred to as I R
19 compensation, thereby permits a conventional 12 V supply module,
20 dropped through said compensation, to be used with a DC motor of
21 lower nominal voltage, in order to maintain the effective
22 constant speed of travel of the cutting head assembly 50 over
23 the eye.

24 Referring now to Figure 4 and again to Figure 9, the drive
25 assembly 80 of the microkeratome device is seen in the preferred
26 embodiment to further include a gear box 81 into which a motor

1 main drive shaft 101 extends. From the gear box 81, and
2 specifically concentrically through an engagement hub 110 as
3 shown in Figures 4 and 5, a cutting assembly main drive shaft
4 operatively extends. The cutting assembly main drive shaft
5 comprises two primary sections, namely: a) a threaded drive
6 screw or "worm" 115 shown in Figure 9, which is an intermediate
7 section that extends through the engagement hub 110; and b) an
8 oscillation shaft 130, also shown in Figure 9, and which is the
9 inner most section and extends through the worm 115.

10 Turning first to the engagement hub 110, shown in Figure 4,
11 it is an outer most section that preferably extends downwardly
12 from the gear box 81 and is structured to be matingly, and
13 preferably threadingly engaged within the threaded aperture 58
14 formed in the main housing 51. As such, the engagement hub 110
15 functions to secure the drive assembly 80 to the cutting head
16 assembly 50. Further, it will be recognized that the drive
17 assembly 80 is thereby permitted to enter the cutting head
18 assembly 50 through a top surface 56' and is thus, generally
19 vertically disposed. It is believed that this feature results
20 in less interference with the surgical field and facilitates
21 finer handling by the surgeon than is offered by conventionally
22 known microkeratomes. Specifically, known microkeratomes have
23 typically provided for horizontally disposed drive means, which
24 resulted in the surgeon having to handle a cord of the driving
25 means, which if not held properly could cause drag on the
26 operation of the microkeratome and/or result in a different

1 pressure being applied to the microkeratome. Moreover, the
2 structure of the present invention maintains its center of
3 gravity substantially over the center of the eye, unlike old
4 systems, thereby providing increased balance and ensuring that
5 the cutting head assembly does not inadvertently tip away from
6 the surface of the eye during use.

7 As illustrated in Figure 5, the oscillation shaft also
8 extends from the gear box 81. Turning now to Figure 9, the
9 oscillation shaft 130, which extends into the housing 51 through
10 its aperture 58, is preferably an independent element that
11 extends concentrically through and protrudes from both ends of
12 the worm 115. The oscillation shaft 130, which is preferably
13 structured to freely rotate relative to the worm 115 includes an
14 upper drive portion 132 which may be welded onto shaft 130 but
15 which is in any event, drivingly engaged with a main drive gear
16 102 secured to the motor main drive shaft 101. Accordingly,
17 rotation of the motor main drive shaft 101 results in
18 corresponding rotation of the oscillation shaft 130. Further,
19 protruding off center from an opposite end 134 of the
20 oscillation shaft 130 is an oscillation pin 135. The
21 oscillation pin 135, which is preferably downwardly biased to
22 maintain engagement pressure on the cutting element 70 is
23 structured to extend into a slot 72' formed in an upper surface
24 of the preferred blade holder 72 or other means 325 formed on
25 the blade holder for receiving the oscillating pin and
26 permitting it to impart movement thereto. As such, upon axial

1 rotation of the oscillation shaft 130, the oscillation pin 135
2 rotates a predetermined radius off center and alternatively
3 engages opposite side edges of the slot 72' of the blade holder
4 72 to result in alternating, oscillating movement of the blade
5 holder 72 and the cutting blade held thereby.

6 Still referring to Figure 9, the oscillating shaft 130
7 further includes a secondary drive portion 133. The secondary
8 drive portion 133 is drivingly connected with a first interior
9 drive gear 103 contained within the gear box 81. The first
10 interior drive gear 103 is connected with and is drivingly
11 secured to an interior drive shaft 104, which preferably
12 includes a second interior drive gear 105 disposed thereon in
13 spaced apart relation from the first interior drive gear 103.
14 As such, upon rotation of the oscillation shaft 130, the second
15 interior drive gear 105 also rotates.

16 Again with reference to Figure 9, drivingly connected with
17 the second interior drive gear 105 and structured to extend from
18 an interior of the gear box 81, concentrically through the
19 engagement hub 110, is the threaded drive screw or "worm" 115.
20 The worm 115, which extends up into the gear box 81 includes a
21 drive head 116 which engages the second interior drive gear 105.
22 As a result, upon rotation of the interior drive shaft 104, the
23 worm 115 correspondingly rotates within the housing 51 of the
24 cutting head assembly 50. Further, rotatably disposed within
25 the housing 51, in operative engagement with the worm 115, is a
26 worm gear 120. The worm gear 120 preferably includes an

1 increase diameter central portion 122 having a plurality of
2 drive recesses formed about a perimeter thereof and structured
3 to engage the exterior threaded surface of the worm 115 such
4 that the central portion 122, and accordingly the entire worm
5 gear 120, rotates about a horizontal axis as a result of the
6 rotation of the worm 115 about a vertical axis. It is noted
7 that the screw-like threaded surface of the worm 115 enables the
8 worm 115 to rotate without moving vertically and successively
9 engage the drive recesses on the worm gear 120 to effect
10 rotation thereof. Extending from at least one, but preferably
11 both vertical faces of the central portion 122 of the worm gear
12 120 is a propulsion shaft 125. The propulsion shaft 125, which
13 comprises additional tracking means, is structured to protrude
14 from the sidewall structure 53 of the main housing 51 and engage
15 the toothed track 43 on the positioning ring 32 such that upon
16 rotation of the worm gear 120, and accordingly rotation of the
17 propulsion shaft 125, the propulsion shaft 125 rides along the
18 toothed track 43 and drives the cutting head assembly 50 across
19 the positioning ring 32 smoothly and at a steady and defined
20 pace. Furthermore, it is seen that by reversing the rotational
21 direction of the interior drive shaft 101 within the gear box
22 81, the direction of rotation of the worm 115 and therefore the
23 worm gear 120 are reversed to effectuate reverse driven movement
24 of the cutting head assembly 50 over the positioning head 32.
25 Also, so as to facilitate movement over toothed track 43 and the
26 arcuate path thereof, it is preferred that the propulsion shaft

1 125 portion of the worm gear 120 include a helical gear
2 configuration or plurality of angled ridges to permit more
3 effective alignment with the curved toothed track 43 and
4 movement thereover.

5 Considering the motor 100, once again, it is preferred that
6 it be controlled by a foot pedal or like actuation means. In
7 the case of a foot pedal, it is preferred that it be a dual
8 function foot pedal such that one side will function to drive
9 the motor main drive gear 101, and therefore the cutting head
10 assembly 50 in a forward direction, and the second side will
11 drive them in a reverse direction. Further, the system may be
12 set to a manual mode whereby a doctor must affirmatively reverse
13 the direction of movement, or an "auto-reverse" mode wherein
14 upon the cutting head assembly 50 traveling its maximum distance
15 it automatically reverses direction. In either case, however,
16 the device will preferably be equipped with a sensor, such as a
17 proximity sensor of any type or as in the preferred embodiment
18 a sensor associated with the motor 100 and structured to detect
19 an abrupt current increase such as that exhibited upon
20 encountering a mechanical stop. Specifically, when the cutting
21 head assembly 50 reaches the stop means 65 and further forward
22 movement is either partially or completely resisted, an abrupt
23 current increase will generally occur in the motor 100. That
24 abrupt current increase, once detected, can signal either the
25 power to shut off, or the reverse movement to commence,
26 depending upon a doctor's desired setting.

1 As has been described, the preferred microkeratome device
2 can be utilized on both eyes of the patient, see Figure 10-A and
3 10-B. Specifically, as worm gear 120 runs through housing 51
4 and juts out of the opposite surrounding sidewall structure 53
5 of housing 51, the cutting head assembly is ready to use on the
6 opposite eye of a patient. In order to accomplish this, and due
7 to the symmetric shape of the cutting head assembly 50, the
8 drive means 80 need only be removed from the housing 51 and
9 thus, coupling member 90, whereupon, it can be re-oriented 180
10 degrees for use with the opposite eye of a patient.

11 Considering the drive assembly 80 once again, it should be
12 noted that it must generally operate in conjunction and in
13 harmony with the suctioning assembly applied to the positioning
14 ring 32 when surgery is performed on an eye. Accordingly, the
15 present invention is further directed towards incorporating both
16 the drive assembly 80 and the suctioning assembly as part of an
17 overall control assembly 200. The control assembly 200 of the
18 present invention includes a portable housing 205 from which
19 power and control are supplied through a cable 203 to the
20 portion of the drive assembly 80 which interacts with the
21 cutting head assembly 50, and from which a vacuum source of the
22 suctioning assembly is supplied through the vacuum hose 202.
23 The suctioning assemblies and the vacuum source which it
24 provides will be addressed first. Specifically, the vacuum
25 source generally includes a vacuum pump 210 contained within the
26 housing 205, which is powered from a conventional power supply,

1 such as an internal or external power module and/or power
2 source, and which operates to create the vacuum which results in
3 a suction at the positioning ring. In addition to the vacuum
4 pump 210, however, the suctioning assembly of the present
5 invention further include a reserve vacuum tank 215. The
6 reserve vacuum tank 215 is structured to be evacuated upon
7 activating the control assembly 200 and maintained generally at
8 an operational level. Moreover, in the event that the operation
9 of the vacuum pump is interrupted, such as due to a power loss,
10 the reserve vacuum tank 215 is preferably structured to maintain
11 a sufficient vacuum to continue the positioning ring's hold on
12 the eye until the movement of the cutting head assembly 50 over
13 the eye is completed. Specifically, the control assembly 200 is
14 structured such that the reserve vacuum tank 215 is preferably
15 continually operational and such that in the event of a power
16 loss or other interruption to the operation of the vacuum pump
17 210, a check valve isolates the vacuum pump 210, the necessary
18 vacuum is maintained by the reserve vacuum tank 215, and a
19 complete cutting pass across the eye is not dangerously and
20 unexpectedly interrupted due to an interruption in the operation
21 of the vacuum pump 210.

22 According to the present invention, the vacuum pump 210 is
23 preferably controlled by a computerized processor control 220
24 within the housing 205. The processor control 220 performs a
25 number of functions at all times including when the control
26 assembly 200 is turned on and/or is in a "Ready" mode. In

1 particular, when the control assembly 200 is first turned on, it
2 is structured to conduct a number of internal tests, as
3 indicated on a display screen 211, and the vacuum pump 210 is
4 preferably directed to first generate a vacuum in the reserve
5 vacuum tank 215. Next, the vacuum pump 210 will preferably
6 continue to run until a desired vacuum relative to atmospheric
7 pressure is generated. Once the desired vacuum is achieved,
8 however, operation of the vacuum pump is cycled. For example,
9 once a desired level is attained, the vacuum pump 210 is turned
10 off until the vacuum drops below a certain point relative to
11 atmospheric pressure. At that point, the vacuum pump 210 is
12 preferably turned on once again by the processor control 220 in
13 order to raise the vacuum back up above the desired level. In
14 this manner, an operable back-up vacuum is available, if ever it
15 should be needed.

16 In the preferred embodiment, the control assembly 200
17 remains in the "Ready" mode until a user wishes to begin an
18 operation or to conduct further testing, if that is desired.
19 When, however, it is time to begin an operation, a user
20 typically presses a foot pedal 216 or other switch to activate
21 the vacuum and shift the control assembly into an "Operating"
22 mode. Before entering the "Operating" mode, a "Pre-op" mode is
23 preferably initiated wherein the control assembly 200 completes
24 a number of internal tests. Unlike the "Ready" mode, once in
25 the "Operating" mode, the vacuum pump 210 will preferably remain
26 on, thereby ensuring that a sufficient vacuum will always be

1 present. Furthermore, so as to ensure that a malfunction in the
2 processor control 220 does not interrupt the cutting process,
3 once the "Operating" mode is entered, control of the motor 100,
4 to be described in greater detail subsequently, is preferably
5 removed/interrupted from the processor control 220, such that
6 the processor control 220 only acts in an advisory capacity as
7 to the performance of the motor 100 and mechanism, providing
8 warning messages and data, and is transferred to an independent
9 logic control 225, such as one embodied in one or more PAL
10 chips. Preferably, this transfer of control is achieved
11 utilizing at least one latching switch 228 connected between the
12 processor control 220 and the independent logic control 225. The
13 latching switch 228 is normally positioned so that the processor
14 control 220 at least partially directs the operation of the
15 motor 100, however, when the "Operation" mode is entered, it is
16 switched so as to eliminate dependency on the processor control
17 220, so that the back up power source 260 becomes operational,
18 and so that the independent logic control 220 directs the
19 operation of the motor 100 without processor influence.
20 Preferably, this "Operation" mode orientation of the latching
21 switch 228 is maintained until affirmatively reset by a user.
22 For example, pressing foot pedal 216 once again will reset
23 control to its "Ready" mode state.

24 Still addressing the suctioning assembly, although the
25 powering of the vacuum pump 210 may require a high voltage, it,
26 as well as all other high voltage aspects of the control

assembly 200, must be isolated from a low voltage portion of the circuitry which comes into contact with the patient. In this regard, in some instances a momentary removal of power to the vacuum pump 215 can sometimes occur, thereby requiring a resetting of certain conditions before the pump can restart and normal running can proceed. For example, in the preferred embodiment, if while in the "Operate" mode the current drawn by the vacuum pump 215 momentarily jumps from approximately .6 amps to approximately 1.3 amps, the control assembly 200 will generally identify a pump restart. If the pump fails to restart, the vacuum reserve tank operates to maintain the vacuum so as to enable a surgery in progress to be completed. Normally, however, the pump is able to restart, and normal running of the vacuum pump resumes. However, even if the vacuum pump is able to restart, the vacuum pump will typically not resume operation if a full vacuum is still present, thereby requiring a momentary release of vacuum prior to achieving the restart. The release of vacuum, however, is triggered from controls on the low voltage side of the control assembly 200. Therefore, the present invention preferably utilizes an optic switching assembly 240 to trigger the momentary release of vacuum with the required electrical isolation. In particular, when the previously described typical current jump associated with a pump restart is exhibited, that current jump typically gives rise to an instantaneous voltage increase from a normal peak of less than .9v to a normal peak of at least 1.25v across

1 a preferably .75 ohm resistor 241, and is sufficient to
2 illuminate an LED 242 of an optic coupler 240'. The LED 242
3 illuminates a light actuated semi conductor 243 of the optic
4 coupler 240' via a galvanically isolated path. Preferably
5 through a pulse extender, a semi-conductor chip 245 is then
6 actuated and in turn actuates a valve 247 to cause the momentary
7 release in vacuum required for the restart and continuing
8 operation of the vacuum pump 210. Accordingly, complete
9 isolation is maintained between the high voltage and low voltage
10 sides of the assembly. Indeed, this process is also utilized
11 during the described pump cycling in the "Ready" mode.

12 Turning now to the other aspect affected by the control
13 assembly 200, namely, the drive assembly 80, it is preferably
14 powered by a motor 100, such as low power DC, pneumatic or
15 hydraulic motor. The motor 100 is sufficient to drive the
16 cutting head assembly 50 across a positioning ring, such as 32,
17 and will preferably operate in both a forward and a reverse
18 direction. Furthermore, during normal forward operation, the
19 control assembly 200 is structured to detect an increase in
20 amperage above a certain predetermined limit, typically a 300
21 milliamp level, which is a typical indication that movement of
22 the cutting head assembly 50 has been blocked and that the
23 activity of the motor 100 and drive assembly is being resisted.
24 A stop of the cutting head assembly 50 can occur either due to
25 the presence of an obstacle on the cutting path over the
26 positioning ring, such as a number of eyelashes or other debris,

1 or due to the normal stopping of the cutting head assembly 50
2 because it has made a complete cut reaching the mechanical stop
3 means. In any event, however, if the motor 100 pulls to the 300
4 milliamp level after a normal 3 second run, the motor 100 shuts
5 off and is dynamically braked until restarted by the user. To
6 restart, in preferably only an emergency situation, the user may
7 temporarily remove pressure from the foot pedal 252 so as to
8 restart and then again activate the foot pedal to result in a
9 continued movement of the motor 100 for another three (3)
10 seconds, during which the only limitation upon the power to the
11 motor 100 is a defined current limit of preferably approximately
12 400 milliamps. Indeed, this more absolute limit of 400
13 milliamps is in effect at all times, including during motion in
14 both the forward and reverse directions.

15 In addition to stopping the operation of the drive assembly
16 80 because of a movement stoppage, in the event of a loss of
17 suction at the positioning ring, which may result in temporary
18 or complete detachment of the positioning ring from the eye, the
19 control assembly 200 is preferably further structured to
20 immediately shut off and dynamically brake the motor 100, and
21 therefore, the drive assembly. As a result, the cutting head
22 assembly 50 will not continue to cut if there is even a
23 momentary break in the suction of the positioning ring to the
24 eye. Moreover, if such a shut down occurs, complete re-
25 initiation of the operating mode, including the normal array of
26 systems checks and the re-establishment of the vacuum, must

1 preferably be achieved before operation of the motor 100 can
2 resume. Still, re-initiation is **never** recommended until after
3 a proper healing period has passed.

4 As indicated, the vacuum pump 210 of the present invention
5 preferably includes a backup, in the form of the vacuum reserve
6 tank 215, that maintains vacuum if the vacuum pump 210 fails,
7 such as due to a power loss. Similarly, the motor 100
8 preferably includes a backup power source 260, such as one or
9 more lithium batteries, disposed within the housing 205 of the
10 control assembly 200. The backup power source 260 is most
11 preferably included within and as part of the control assembly
12 200 and functions to immediately continue to supply operating
13 power to the motor 100 in case of a power loss from a typical
14 power supply, whether an internal module and/or external source.
15 As such, a completed pass across the eye can be normally
16 completed if a power failure occurs.

17 Lastly, it is noted that in some instances a user that is
18 monitoring patient conditions may already be viewing a computer
19 display console that monitors other patient conditions. As
20 such, the control assembly 200 of the present invention includes
21 a connection port 265, such as a serial connection port, through
22 which a computer interface can be achieved and through which
23 data relating to the operation of the control assembly 200 can
24 be transmitted for convenient use and display on the computer
25 display console. An electrically isolated, bi-directional

1 computer port, such as an RS232 port with optically isolated
2 data and transformer isolated power is preferred for
3 communication with a host laser system or isolated computer
4 system. For example, the laser systems typically employed in
5 the corrective procedures generally include an elaborate
6 computer control. This laser computer control directs the
7 corrective procedure and monitors the status of the operation
8 throughout. As such, by interfacing the control assembly 200
9 with the laser computer control, the actual operating conditions
10 of the present invention can be equivalently monitored and
11 recorded.

12 Since many modifications, variations and changes in detail
13 can be made to the described preferred embodiment of the
14 invention, it is intended that all matters in the foregoing
15 description and shown in the accompanying drawings be
16 interpreted as illustrative and not in a limiting sense. Thus,
17 the scope of the invention should be determined by the appended
18 claims and their legal equivalents.

19 Now that the invention has been described,